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**Efficacy of Endovascular Thrombectomy in patients with M2 Segment Middle Cerebral  
Artery Occlusions: Meta-analysis of data from the HERMES Collaboration**

Cover title: Endovascular therapy in M2 MCA occlusions

Keywords: acute ischemic stroke, endovascular therapy, M2 segment, middle cerebral artery

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## **Abstract**

**Background:** The Society of Neurointerventional Surgery (SNIS) revised its' operational definition of Emergent Large Vessel Occlusion (ELVO) recently to include proximal M2 segment MCA occlusions. We sought to assess the benefit of EVT over best medical care for M2 segment MCA occlusion.

**Methods:** Patient level data from trials in the HERMES Collaboration were included. The HERMES core lab identified patients with M2 segment MCA occlusions and further classified as proximal vs. distal, anterior vs. posterior division and dominant vs. co-dominant vs. non-dominant. Primary outcome was mRS 0-2 at 90 days. Secondary outcomes were mTICI rates at end of procedure, 90-day mRS shift, 90-day mRS 0-1, 24 hr NIHSS 0-2, symptomatic ICH and death.

**Results:** 130 patients with M2 MCA (proximal location n=116 vs. distal n=14, anterior division n=72 vs. posterior n=58, dominant n=73 vs. co-dominant n=50 vs. non-dominant n=7) were included. Successful reperfusion (mTICI 2b or 3) among those undergoing EVT was seen in 59.2% patients. Treatment effect favored EVT (adjusted OR 2.39, 95% CI 1.08-5.28, p=0.03) for 90-day mRS 0-2 (58.2% EVT vs. 39.7% control). Direction of benefit favored EVT for other outcomes. Treatment effect favoring EVT was maximal in patients with proximal M2 segment MCA occlusions (n=116, adjusted OR 2.68, 95% CI 1.13-6.37) and in dominant M2 segment MCA occlusions (n=73, adjusted OR 4.08, 95% CI 1.08-15.48). No sICH (0%) was observed in patients treated with EVT compared to 5 (7.8%) in the control arm.

**Conclusion:** Patients with proximal M2 segment MCA occlusions eligible for EVT trial protocols benefited from EVT.



## Introduction

Endovascular thrombectomy (EVT) works by recanalizing intracranial arteries in a timely and safe manner, saving ischemic brain from irreversible injury.<sup>1</sup> The presence of salvageable brain tissue along with a target arterial occlusion that could be recanalized in a time bound manner and the safety of the procedure during such an attempt were the primary reasons why recent clinical trials showed efficacy of EVT over standard care.<sup>2 3</sup> In an effort to establish a beachhead of evidence for EVT during a time when prior trials had shown lack of efficacy of EVT, trials published in 2015-17 focused on the more accessible, larger vessel anterior circulation (internal carotid artery and M1 segment middle cerebral artery) occlusions.<sup>4</sup> These occlusion sites also lend themselves easily to imaging selection strategies used in these trials (e.g. NCCT ASPECTS, CTP ischemic core volume or CTA collateral assessments).<sup>5 6</sup> Patients with M2 segment MCA occlusions were either deliberately excluded (e.g. in the ESCAPE, SWIFT PRIME, REVASCAT, THRACE and PISTE trials) or were under-sampled (e.g. in the MR CLEAN and the EXTEND IA trials).<sup>2</sup> Questions about efficacy of EVT in patients with M2 segment MCA occlusions remain.<sup>7-9</sup>

Many proximal M2 MCA segment occlusions are as easily accessible for EVT as M1 segment MCA occlusions.<sup>8</sup> Some M2 segment MCA arteries are the dominant artery supplying blood to a large portion of the MCA territory.<sup>10</sup> A recent meta-analysis of data from 12 non-randomized studies suggested that EVT for patients with M2 segment MCA occlusions that can be safely accessed is associated with high recanalization rates and good clinical outcomes.<sup>7</sup> Using patient level data from the HERMES (Highly Effective Reperfusion evaluated in Multiple Endovascular Stroke Trials) Collaboration therefore, we sought to test the hypothesis that EVT would result in

better clinical outcomes among patients with M2 segment MCA occlusions when compared to standard care. In addition, we asked whether certain anatomical characteristics of M2 segment MCA occlusions such as location, size, anatomy and number of vessels occluded lend themselves better to EVT than others.

## **Methods**

The HERMES collaboration includes patient level data from the MR CLEAN, ESCAPE, REVASCAT, SWIFT PRIME, THRACE, EXTEND IA and PISTE randomized controlled trials. Differences in patient population, sampling frame and operational definitions of intervention (EVT) and control have been published previously.<sup>6</sup> All baseline imaging was read by the HERMES central core lab blinded to clinical information. The core lab identified thrombus location at baseline on CT Angiography (preferably) or MR Angiography. Thrombus location was classified as either internal carotid artery (ICA), proximal and distal M1 segment middle cerebral artery (MCA) or M2 segment MCA. An occlusion was considered to be in the distal M1 segment MCA and not in a M2 segment MCA if the only patent MCA arterial branch proximal to the occlusion was the anterior temporal artery.<sup>10 11</sup> The M2 segment MCA with thrombus was sub-classified based on a) location (assessed on coronal images; proximal to the mid-sylvian point vs. distal) b) vascular territory supplied [anterior division (supplying the anterior MCA region) vs. posterior (supplying the posterior MCA region)] c) size [dominant division (supplying >50% of the MCA territory) vs. co-dominant (50% of the MCA territory) vs. non-dominant (<50% of the MCA territory)] and d) number (one branch involved vs. more than one). Subject count included in analyses by trial were MR CLEAN (n=46), ESCAPE (n=18),

EXTEND-IA (n= 9), SWIFT PRIME (n=24), REVASCAT (n=21), PISTE (n=4) and THRACE (n=8).

Since M2 segment MCA occlusions only cause ischemia to a part of the MCA territory, it is reasonable to assume that patients with such occlusions are less likely to have large infarcts that are more commonly associated with a bed ridden state or death even when not treated with EVT. Maximal benefit with EVT vs. standard care is therefore likely to be seen on the lower end of the modified Rankin Scale with minimal gains across higher levels of this scale.<sup>12</sup> We therefore chose functional independence (mRS 0-2) as the primary outcome for this analysis. Secondary outcomes included excellent functional outcome (mRS 0–1) at 90 days, shift in mRS distribution at 90 days and dramatic neurological improvement (defined as NIHSS 0-2 24 hours after stroke onset). Technical efficacy was assessed by revascularization at end of endovascular procedure defined using modified Thrombolysis in Cerebral Infarction (mTICI) scale score of 2b or 3, corresponding to reperfusion of at least 50% of the affected vascular territory. Safety outcomes included symptomatic intracranial hemorrhage (sICH; defined by each trial) and death within 90 days.

### **Statistical Analysis**

All analyses were by intention to treat. Mixed-effects modeling was used for all analyses, with fixed effects for parameters of interest and “trial” and the interaction term “trial\*treatment” as random effects variables in all models. All adjusted regression models (binary logistic and ordinal) included fixed effects (age, sex, NIHSS score at admission, intravenous alteplase use and time from onset to randomization). Heterogeneity of treatment effect by pre-specified

clinical sub-groups [age  $\leq 70$  vs.  $> 70$  years, sex, NIHSS score at admission ( $\leq 10$ , 11-15,  $> 15$ ), baseline NCCT ASPECTS ( $\leq 8$  vs. 9-10), intravenous alteplase use and time from stroke onset to randomization  $\leq 300$  mins vs.  $> 300$  mins) was assessed. Treatment effect in M2 segment MCA sub-types with sufficient sample size were also reported. All statistical analyses were performed using SAS v.9.2 (SAS Institute, Cary, North Carolina).

### **Role of the funding source**

The funders of the study had no role in study design, data analysis, data interpretation, or writing of the report.

### **Results**

Baseline characteristics and workflow processes of patients with M2 segment MCA occlusions in the EVT and control groups are described in Table 1. After excluding one patient with missing 90-day outcome, 130 patients with M2 segment MCA occlusions (proximal location  $n=116$  vs. distal  $n=14$ , anterior division  $n=72$  vs. posterior division  $n=58$ , dominant  $n=73$  vs. co-dominant  $n=50$  vs. non-dominant  $n=7$ , single vessel  $n=123$  vs. multi-vessel  $n=7$ ) were included for further analysis. Sixty-seven patients were randomised to the EVT arm and 63 patients to the control arm. Successful reperfusion (mTICI 2b or 3) was observed in 59.2% patients. Infarct core volumes at baseline were assessed on 64 patients (51 subjects using baseline CTP vs. 13 baseline MRI). Median core volume was 12.6 ml (IQR 2.9, 28.6) by central assessment.

Figure 1 shows the distribution of mRS in the intervention arm vs. control in all patients included



in this analysis. Treatment effect favored EVT over control (adjusted OR 2.39, CI<sub>95</sub> 1.08-5.28, p=0.03) for mRS 0-2 at 90 days. The corresponding unadjusted odds ratio was 2.13 (CI<sub>95</sub> 1.05 – 4.35; p=0.04; 58.2% with EVT vs. 39.7% control respectively) while the number needed to treat for 1 patient to have functional independence (mRS 0-2) was 5.4. The direction of benefit favored EVT over control for other outcomes, but results were not conventionally statistically significant (Table 2). No sICH or major procedural complications (0%) were noted among patients treated with EVT compared to 5 (7.8%) in the control arm. Death at 90 days occurred in 11.9% patients in the EVT group vs. 9.5% in the control group (p=0.66). No statistically significant heterogeneity in treatment effect was noted by age, sex, NIHSS score at admission, baseline NCCT ASPECTS, intravenous alteplase use and time from stroke onset to randomization (all p>0.05).

Treatment effect favoring EVT was maximal in patients with proximal M2 segment MCA occlusions (n=116, adjusted OR 2.68, 95% CI 1.13-6.37, p=0.02 for mRS 0-2 at 90 days, 57.1% EVT vs. 37.7% control, respectively), when the involved M2 segment MCA was dominant (n=73, adjusted OR 4.08, 95% CI 1.08-15.48, p=0.04 for mRS 0-2 at 90 days, 61.5% EVT vs. 44.1% control, respectively) and when a single M2 segment MCA was involved (n=123, adjusted OR 2.73, 95% CI 1.19-6.27, p=0.02 for mRS 0-2 at 90 days, 58.5% EVT vs. 37.9% control, respectively). The direction of benefit favored EVT for these sub-types of M2 segment MCA occlusion across most secondary outcomes. (Table 3) Benefit with EVT was seen in patients with anterior and posterior division M2 segment MCA occlusions, although smaller sample sizes meant results did not reach statistical significance (results not shown). No statistically significant heterogeneity in treatment effect however was noted across any M2

segment MCA occlusion type.

## **Discussion**

Endovascular therapy is now standard care in patients with ischemic stroke due to emergent anterior circulation large vessel occlusions.<sup>13</sup> The Society of Neurointerventional Surgery (SNIS) recently revised its' operational definition of Emergent large vessel occlusion Large Vessel Occlusion (ELVO) to include proximal M2 segment MCA occlusions in addition to intracranial carotid artery and M1 segment MCA occlusions.<sup>8</sup> The American Stroke Guidelines assign this occlusion site a lesser degree of evidence of benefit with EVT when compared to the internal carotid artery or M1 segment MCA occlusions.<sup>14</sup> This analysis of patients with M2 segment MCA occlusions from the HERMES Collaboration of 7 recent randomized controlled trials shows that EVT, especially in patients with proximal or dominant M2 segment MCA, results in improvement in functional ability at 90 days when compared to best medical care.

Mechanical embolectomy devices are designed to suit the target arterial profile and access. Devices that work well in the proximal arterial segments are less likely to suit the arterial profile and access demands of distal arterial segments. A proximal segment or dominant M2 MCA branch however does not necessarily pose significantly increased difficulty in access when compared to the distal M1 segment MCA. This is substantiated by the fact that our analysis showed no intracerebral hemorrhage or major procedural complications in these patients. Moreover, patients with dominant M2 MCA branch occlusions have substantial volume of ischemic brain that could potentially be salvaged with EVT, thus increasing chances of benefit with this therapy. The successful reperfusion (mTICI 2b/3) rates noted in this analysis (59.2%)

are significantly better than that obtained with intravenous alteplase in patients with M2 segment MCA occlusions.<sup>15</sup> The reperfusion rates with EVT could improve further with the use of smaller diameter, next generation, stent retrievers and aspiration devices, further improving clinical outcomes in these patients.<sup>16 17</sup>

Functional independence rates at 90 days noted in this study are comparable to results from a recent meta-analysis of 12 non-randomized studies reporting outcomes in patients with M2 segment MCA occlusions treated with EVT (58.2% vs. 59% 90-day mRS 0-2 rates respectively).<sup>7</sup> Interestingly, successful recanalization rates in these 12 non-randomized studies (81% overall) were higher than that noted in the current study (59.2%) while the symptomatic ICH (10% vs. 0%) and death (16% vs. 11.9%) rates were higher, highlighting the need for good patient selection and the use of appropriate endovascular techniques in these patients.

Although this analysis represents high-quality randomized trial data, caution in interpretation is warranted. Differences in baseline characteristics (e.g. median baseline ASPECTS 9 in the EVT group vs. 8 in the control group, difference not statistically significant) may potentially explain better outcomes in the EVT group. The seven recent RCTs testing EVT efficacy included in the HERMES Collaboration did not include all patients with M2 segment MCA occlusions (by design or otherwise).<sup>6</sup> We cannot therefore rule out the possibility of selection bias influencing these results. Only 130 patients were available for analysis, potentially resulting in analysis of effect modification by M2 segment MCA occlusion type being underpowered to show efficacy of EVT. Nonetheless, point estimates of all reported clinical outcomes favouring EVT provides confidence that EVT benefits these patients. Finally, the choice of the primary outcome (mRS 0-

2 proportion at 90 days) was based on a careful assessment of the outcome distribution on the mRS scale and may therefore be considered post-hoc.<sup>12</sup>

In conclusion, this analysis from recent randomized controlled trials provides additional evidentiary support for the efficacy of EVT vs. current non-endovascular acute stroke therapy in patients with M2 segment MCA occlusions.

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## Tables

**Table 1:** Baseline characteristics and workflow processes in patients with M2 segment MCA occlusions in endovascular therapy (EVT) and control groups.

Characteristic	Endovascular Treatment Group Mean $\pm$ Standard Deviation (N=67) [Median] (Inter-quartile Range)	Control Group Mean $\pm$ Standard Deviation (N=64*) [Median] (Inter-quartile Range)	P value
Age (years)	66.0 $\pm$ 13.7 (67) [66.4] (56.9,76.0)	65.2 $\pm$ 12.0 (64) [65.9] (57.9,75.0)	0.71
Sex (Female, %)	53.7% (36/67)	46.9% (30/64)	0.49
History of Hypertension (%)	61.2% (41/67)	59.4% (38/64)	0.86
History of Dyslipidemia (%)	36.9% (24/65)	35.9% (23/64)	1.00
History of Diabetes mellitus (%)	16.4% (11/67)	21.9% (14/64)	0.51
Atrial fibrillation (%)	38.1% (24/63)	28.3% (17/60)	0.34
NIHSS at baseline	14.4 $\pm$ 5.1 (67) [14.0] (11.0,19.0)	15.4 $\pm$ 6.0 (63) [15.0] (11.0,20.0)	0.32
Baseline Non-contrast CT ASPECTS	8.6 $\pm$ 1.4 (67) [9.0] (8.0,10.0)	8.1 $\pm$ 1.6 (64) [8.0] (7.0,10.0)	0.06
Intravenous alteplase administered	85.1% (57/67)	89.1% (57/64)	0.61
Stroke onset to intravenous alteplase bolus (mins)	119.6 $\pm$ 54.3 (56) [107.5] (83.8,136.3)	113.5 $\pm$ 44.8 (57) [100.0] (84.0,140.0)	0.52
Stroke onset to randomization (mins)	199.5 $\pm$ 84.1 (67) [180.0] (147.5,250.5)	209.0 $\pm$ 76.5 (63) [193.0] (152.5,264.0)	0.50
Stroke onset to groin puncture (mins)	238.2 $\pm$ 90.3 (61) [220.0] (90.0,599.0)	-	-

NIHSS, National Institute of Health Stroke Score; ASPECTS, Alberta Stroke Program Early CT Score

\*one patient with missing 90-day outcome was excluded from outcome analysis



**Table 2:** Unadjusted and adjusted clinical and safety outcomes in patients with M2 segment MCA occlusions.

Outcome	Endovascular Treatment Group % (n/N)	Control Group % (n/N)	Unadjusted		Adjusted	
			Odds Ratio (95% CI)	p-value	Odds Ratio (95% CI)	p-value
mRS 0-2	58.2% (39/67)	39.7% (25/63)	2.13 (1.05-4.35)	0.04	2.39 (1.08-5.28)	0.03
mRS at 90 days	N/A	N/A	1.88 (1.01-3.49)	0.05	1.77 (0.94-3.36)	0.08
mRS 0-1	37.3% (25/67)	20.6% (13/63)	2.62 (0.92-7.45)	0.07	2.71 (0.83-8.83)	0.10
NIHSS 0-2 at 24h	26.9% (18/67)	8.2% (5/61)	4.11 (1.42-11.9)	0.01	3.82 (1.22-11.95)	0.02
sICH	0.0% (0/67)	7.9% (5/63)	0	0.03	--	--
Death	11.9% (8/67)	9.5% (6/63)	1.29 (0.42-3.95)	0.66	1.33 (0.38-4.7)	0.66

mRS, modified Rankin Scale; NIHSS, National Institute of Health Stroke Score; sICH, symptomatic intracerebral hemorrhage



**Table 3:** Unadjusted and adjusted clinical and safety outcomes in patients with proximal M2 segment MCA occlusion, single vessel M2 segment middle cerebral artery (MCA) occlusions and dominant M2 segment MCA occlusions.

			Unadjusted		Adjusted	
Outcome	Endovascular Treatment Group % (n/N)	Control Group % (n/N)	Odds Ratio (95% CI)	p-value	Odds Ratio (95%)	p-value
<b>Proximal M2 segment MCA (n=116)</b>						
mRS 0-2	57.1% (36/63)	37.7% (20/53)	2.24 (1.04-4.81)	0.04	2.68 (1.3-6.37)	0.027
mRS at 90 days	N/A	N/A	1.96 (1.01-3.8)	0.048	1.95 (0.98-3.87)	0.059
mRS 0-1	36.5% (23/63)	18.9% (10/53)	3.07 (0.95-9.9)	0.063	3.03 (0.81-11.24)	0.101
NIHSS 0-2	28.6% (18/63)	5.9% (3/51)	6.4 (1.77-23.21)	0.005	6.09 (1.55-23.99)	0.011
sICH	0.0% (0/63)	7.5% (4/53)	0	0.041	--	--
Death	11.1% (7/63)	7.5% (4/53)	1.53 (0.42-5.55)	0.518	1.58 (0.38-6.63)	0.532
<b>Dominant M2 segment MCA (n=73)</b>						
mRS 0-2	61.5% (24/39)	44.1% (15/34)	1.91 (0.72-5.1)	0.198	4.08 (1.08-15.48)	0.042
mRS at 90 days	N/A	N/A	1.96 (0.84-4.6)	0.125	2.76 (1.07-7.11)	0.039
mRS 0-1	35.9% (14/39)	17.6% (6/34)	3.04 (0.6-15.31)	0.182	3.69 (0.8-16.91)	0.098
NIHSS 0-2	33.3% (13/39)	3.0% (1/33)	16 (1.96-130.5)	0.016	40.42 (3.3-495.48)	0.005
sICH	0.0% (0/39)	5.7% (2/35)	0	0.22	--	--
Death	5.1% (2/39)	5.9% (2/34)	0.86 (0.12-6.5)	0.8882	0.22 (0.02-2.35)	0.215
<b>Single vessel M2 segment MCA (n=123)</b>						
mRS 0-2	58.5% (38/65)	37.9% (22/58)	2.34 (1.12-4.91)	0.025	2.73 (1.19-6.27)	0.019
mRS at 90 days	N/A	N/A	2.03 (1.07-3.86)	0.033	1.92 (0.99-3.73)	0.054
mRS 0-1	38.5% (25/65)	19.0% (11/58)	3.2 (1.06-9.71)	0.042	3.24 (0.93-11.29)	0.067

NIHSS 0-2	27.7% (18/65)	7.1% (4/56)	4.98 (1.57-15.77)	0.007	4.98 (1.43-17.34)	0.01
sICH	0.0% (0/65)	6.8% (4/59)	0	0.048	--	--
Death	10.8% (7/65)	6.9% (4/58)	1.62 (0.45-5.85)	0.464	1.69 (0.4-7.08)	0.477

mRS, modified Rankin Scale; NIHSS, National Institute of Health Stroke Score; sICH, symptomatic intracerebral hemorrhage

## Figures

**Figure 1:** Modified Rankin Scale (mRS; unadjusted) distribution at 90 days in patients with baseline CT or MR Angiography defined M2 segment middle cerebral artery (MCA) occlusions. Benefit with endovascular thrombectomy (EVT) is better seen on the left side of the mRS scale.

